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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,726

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EXAMINER

BERTAGNA, ANGELA MARIE

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,726	Applicant(s) AMONTOV ET AL.	
	Examiner ANGELA BERTAGNA	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-17 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-17 and 20-22 is/are rejected.
- 7) ☒ Claim(s) 15-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/6/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 6, 2009 has been entered.

Claims 1, 4-17, and 20-23 are currently pending. In the response, Applicant amended claim 1. Claim 23 remains withdrawn as being drawn to a non-elected invention.

Applicant's amendments to the claims have overcome all of the previously made rejections, and therefore, they have been withdrawn. The following are new grounds of rejection.

Information Disclosure Statement

2. Applicant's submission of an Information Disclosure Statement on April 6, 2009 is acknowledged. A signed copy is enclosed. It is noted that the citations of three cited non-patent literature references contained in the IDS have been corrected to include the pages of the references as required by 37 CFR 1.98(b)(5).

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Claim Objections

3. Claims 15 and 16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 15 depends from claim 14, which depends from the method of claim 1. Claim 15 recites that the polymerase chain reaction of claim 14 comprises binding at least one primer to the surface. Claim 16 depends from claim 15 and recites that the method of claim 15 comprises applying a primer in solution during the amplification step. Since the method of claim 1 excludes any diffusive component in the monolayer, claims 15 and 16, which utilize diffusive components (*i.e.* solution-phase primers), are not further limiting.

Claim 17 is objected to because of the following informalities: This claim appears to be missing words such as "the use of" after the word "comprises". Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-17, and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1, 4-17, and 20-22 are rejected under 35 U.S.C. 112, second paragraph, because the relationship between the "flat surface" recited in line 10 of independent claim 1 and "the surface" recited in the remainder of the claim is unclear. In particular, it is unclear from the claim language whether the claimed method utilizes a single, flat surface, or if a plurality of different surfaces are utilized. Since the scope of the claimed methods is unclear, claims 1, 4-17, and 20-22 are indefinite.

Claim 17 is further indefinite, because it is not clear from the claim language as to how one can produce a monolayer of protein on the surface that is homogeneous from seed molecules that must be either double-stranded DNA or single-stranded mRNA. It is not clear how conducting an *in vitro* translation reaction from such seed molecules would produce the homogeneous monolayer required by the claims, and therefore, claim 17 appears to be missing an essential method step(s).

Claim Rejections - 35 USC § 112, 1st paragraph (New Matter)

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-17, and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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Section 2163.03 of the MPEP states, "An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)."

Section 2163.05 of the MPEP states, "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

Claims 1, 4-17, and 20-22 are drawn to a method for using amplification to form a monolayer of molecules on a surface. The method comprises transferring a fraction of seed molecules from a stamp to a surface and amplifying the seed molecules to form the monolayer. Independent claim 1 has been amended to recite that "the monolayer of molecules on the surface has no diffusive component that can relocate and destroy amplification accuracy". This recitation prohibits the presence in the monolayer of any component (*e.g.* a nucleic acid or protein molecule, ions, buffers, detergents, *etc*) that is capable of diffusing away from the monolayer and destroying amplification accuracy.

Applicant states that this limitation finds support in Figure 1, page 14, and page 17 (see page 5 of the response).

The original disclosure has been carefully reviewed, but the above limitation does not appear to find adequate support therein. The portions of the disclosure cited by Applicant appear to indicate that the preferred monolayer is comprised only of single-stranded nucleic acids, which cannot diffuse away from their location and compromise amplification accuracy. However, the specification fails to provide support for the production of monolayers that are free of all diffusive components that can relocate and destroy amplification accuracy, since the

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monolayers produced by the disclosed methods inherently contain other diffusive components that can relocate and destroy amplification accuracy (*e.g.* ions, buffers, detergents, etc). Thus, the original disclosure does not provide adequate support for the requirement in independent claim 1 for the monolayers produced by the method to be free of diffusive components that can relocate and destroy amplification accuracy. Accordingly, claims 1, 4-17, and 20-22 have been rejected under 35 U.S.C. 112, first paragraph for incorporating new matter.

Response to Arguments

6. As noted above, all of the previously made rejections have been withdrawn in view of the amendment. Accordingly, Applicant's arguments filed on April 6, 2009 have been considered, but they are moot in view of the new grounds of rejection presented above.

Conclusion

7. No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANGELA BERTAGNA whose telephone number is (571)272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

amb

/Kenneth R Horlick/

Primary Examiner, Art Unit 1637